

REMARKS

Claims 1-12 are pending in this application. The claims have been amended to remove reference numerals and to correct improper multiple dependencies. No new matter has been added.

1. Claim Rejections under 35 U.S.C. §112, second paragraph

The Examiner has rejected the claims as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner notes that the claims are replete with vague and indefinite terms and grammatical errors. The Examiner believes that this may be due to the fact that the claims are a "direct translation" from a foreign document. First, Applicant would point out that the priority document, although filed in Finland, was filed in the English language. The claims therefore have not been translated. Second, with respect to the idiomatic and grammatical errors in the claims, Applicant notes that the Examiner has not specifically identified these apparent errors. After reviewing the claims, Applicant could not readily determine what was objectionable to the Examiner. Clarification is requested. Finally, with respect to the Examiner's comments regarding the vague and indefinite terminology of the claims such as "taps", "pretreatment layers", etc., Applicant would point out that the meaning of these terms are specifically set forth in the "Definitions" section of Applicant's Specification (see page 5 et seq.). In view of this disclosure, Applicant submits that the skilled artisan could readily determine the meaning of these terms and the metes and bounds of the claims. As noted in MPEP 2173.03, the test for definiteness under 35 U.S.C. §112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification". *Orthokinetics*,

Appl. No. 10/089,541

Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986).

If one skilled in the art is able to ascertain the meaning of the terms in light of the Specification, 35 U.S.C. §112, second paragraph, is satisfied. Accordingly, Applicant believes that the claims comply with the standards of 35 U.S.C. §112, second paragraph and has not amended the claim language. Reconsideration and removal of the indefiniteness rejection is respectfully requested.

2. Claim Objections

The Examiner has objected to claims 9-12 under 37 C.F.R. 1.75 (c) as being in improper form and has indicated that these claims have not been substantively examined. Applicant has amended the dependency of these claims to obviate the objection. Reconsideration and removal of the objection is requested.

3. Claim Rejections under 35 U.S.C. §102(b)

Claims 1-8 have been rejected under 35 U.S.C. §102(b) as being clearly anticipated by EP 0582231 (Rosenstein), EP 03223605 (Devereaux) and EP 0806666 (Lee). The Examiner argues that each of these references teach a test strip system comprised of multiple bilious layers (some of which containing reagents) enclosed in a casing having a cover/lid with opening to permit sample introduction. Applicants respectfully traverse the rejection.

It is axiomatic that to anticipate a claim, the cited prior art reference must teach every element of the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). If the reference fails to disclose exactly what is claimed, an anticipation rejection cannot stand. Applicant submits that in the present instance, none of the

Appl. No. 10/089,541

cited prior art references teaches each and every element of the claimed invention. The presently claimed test device differs from the prior art devices in two respects. First, the claimed test device comprises a pretreatment system having one or more layers in capillary flow connection with the test strip, wherein said pretreatment system is covered and protected by a lid with an aperture and wherein said lid and lid-portion are provided with means to form an excess fluid collecting compartment. Second, the pretreatment system is provided where different layers are fixed by means (taps, flanking supports and bars) their position. The present invention is thus related to the lid-provided backing support of the test device (i.e. the plastic casing, comprising the filtering means and the test strip). The casing is provided with the means which enable controlled regulation of the flow of fluids, i.e. sample solution and diluent flow. Specifically, the use of several means (7, 8 and 9) for securing and fixing the position of the layers and including a bar which forms an excess fluid collecting compartment behind the pretreatment layers means that all excess fluid is absorbed into the test strip and the negative backwash effect of excess or redundant fluid is avoided. Applicant submits that these features are not disclosed or suggested by the Rosenstein, Lee or Devereaux references and the Examiner has failed to identify any such teachings.

In view of the foregoing remarks, Applicant submits that the cited prior references fail to anticipate the claimed invention because they fail to teach each and every element of the claimed device, in particular, a lid and lid-portion provided with the means to form an excess fluid collecting compartment. As such, Applicant submits that the anticipation rejections are improper and respectfully requests reconsideration and removal of the same.

Appl. No. 10/089,541

Favorable consideration and early allowance of all the claims is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson (Reg. No. 30,330) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

Certificate of Transmission
I hereby Certify that this correspondence is being
facsimile transmitted to the Patent and
Trademark Office.
On January 3, 2005
[Signature]
Sandra P. Paulo
Typed or printed name of person signing certificate

By [Signature] #46,183
Leonard R. Svensson, #30,330

LRS/KR
1390-0129P

P.O. Box 747
Falls Church, VA 22040-0747
(714) 708-8555